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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,765	09/15/2003	David H. Kil	14255-035001 / ARC01-201	1510
26161 7590 07/24/2009 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER SIMS, JASON M	
			ART UNIT 1631	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/662,765	Applicant(s) KIL, DAVID H.	
	Examiner JASON M. SIMS	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 19-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 30-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments, filed 4/21/2009, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 4/21/2009, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Claims 19-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventive group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/20/2006.

Claims 1-18 and 30-36 are the current claims hereby under examination.

Claim Rejections - 35 USC § 101-Maintained

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-18 and 30-36 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter.

Claims 1-18 and 30-36 are drawn to a process. A process is statutory subject matter under 35 U.S.C. 101 if: (1) it is tied to a particular machine or apparatus or (2) it transforms an article to a different state or thing (In re Bilski, 88 USPQ2d 1385 Fed. Cir. 2008).

In the instant case, the claims are drawn to a method for image analysis. The recited process involves the abstract and computational steps of transforming an image, selecting regions of interest, extracting features, ranking features and classifying the image. As such, the instant claims do not recite any tie to a particular machine or apparatus, nor do the instant claims involve a transformation of a particular article. Rather, the instant claims are drawn only to an abstract process that only manipulates data and, therefore, are not directed to statutory subject matter.

The claimed subject matter is not limited to a particular apparatus or machine. To qualify as a statutory process, the claims should require use of a machine within the steps of the claimed subject matter or require transformation of an article to a different state or thing. Insignificant extra-solution activity in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter (*In re Grams* 12 USPQ2d 1824 Fed. Cir.1989). Preamble limitations that require the claimed process to comprise machine implemented steps will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. The applicants are cautioned against introduction of new matter in an amendment.

Response to Arguments

Applicant's arguments filed 4/21/2009 have been fully considered but they are not persuasive.

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Applicant argues that the amendment to recite a step of outputting analysis results to a computing device causes said method to recite a tie to a statutory category of invention.

Applicant's arguments are not found persuasive because said amendment is considered insignificant extra-solution/ post-solution activity in the claimed subject matter, which is not considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter (In re Grams 12 USPQ2d 1824 Fed. Cir.1989).

The following rejection has been modified, which has been necessitated by amendment:

Claim Rejections - 35 USC § 103-Modified

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-18 and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parsons et al. (US P/N 6, 757,412) in view of Curry et al. (US A/N 2003/0219151) in view of Sabol et al. (US 2004/0052328) in view of Echauz et al. (US A/N 2002/0103512) and further in view of Levenson et al. (US P/N 6, 750, 964).

The claims are directed to a method of image analysis comprising transforming an image into a feature space, extracting features, ranking the extracted features, classifying the image into regions of interest, and transmitting the regions of interest for laser capture microdissection.

Parsons et al. teaches limitations of claims 1-2 at col. 14, lines 3-67. Parsons et al. teaches a method of image analysis at the pixel level of processing. Parsons et al. teaches analyzing tissue image data for classification. First a region of interest is selected and each pixel within the region of interest is analyzed and eventually classified using a classifier, which reads on running the classification algorithm to classify the first image or a second image into one or more ROIs at a pixel level of processing, wherein the first or second image selected for classification is a classified image. The images have already been classified into regions of interest using diagnostic modalities, such as mammogram or ultrasound, etc. Then within the region of interest each pixel is analyzed and classified. For each pixel, features are extracted, wherein a feature vector is derived for each pixel as discussed at col. 14, lines 32-37. The feature vector is comprised of feature values for that pixel, such as the temperature response at a corresponding spatial region, which reads on transforming an image into

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feature space and extracting two or more features from each pixel from the ROI at a pixel level of processing.

Parsons et al. suggests, but does not explicitly teach extracting features from a non-ROI and using the features from both a non-ROI and ROI for successful detection of a selected ROI at a pixel level of processing.

Parsons et al. suggest this because Parsons et al. at col. 5, lines 55-67 through col. 7 teach a method of acquiring an image. Parsons et al. at col. 7, lines 40-45 teach developing a classifier wherein feature values from image sets are selected and used. Parsons et al. at col. 8, lines 20-24 teach selecting a ROI from a particular image set of a particular class. Parsons et al. further teach at col. 8, lines 27-28 that each pixel in the ROI may be modeled individually, wherein a model essentially extracts features and quantifies the temporal and spatial characteristics of each pixel. Parsons et al at col. 14, lines 40-45 teach that different features may be selected to quantify different attributes for each pixel in the ROI. Parsons et al. teach that each pixel in a region of interest is processed, wherein particular pixels and their respective features may be chosen for creating a classifier. Therefore the use of selected feature data from some pixels and not from other pixels, but processing and extracting features from all pixels in an ROI, reads on the broad and reasonably interpreted wording wherein a user selects particular pixels, some which may be used and others which may not be used in the instant application. Furthermore, Parsons et al. at col. 14, lines 45-48 discusses how a classifier is applied to each feature vector for each pixel for classification and a

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determination is made about the likelihood values indicating the likelihood that the associated spatial region of the tissue belongs to a particular class of tissue.

Curry et al. at the abstract and paragraphs [0039] – [0040] teach a method for extracting features from both a ROI pixels and non-ROI (i.e. background pixels), wherein the features are used to distinguish background pixels, i.e. non-ROI, from ROI pixels. In other words, Curry et al. utilizes non-ROI pixel information for the successful detection of a selected ROI at a pixel level of processing.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have used the classification of pixels for the successful detection of a selected ROI as taught by Curry et al. with the image processing method taught by Parsons et al. This is because it is desirable to have a background control wherein one of ordinary skill in the art can use local backgrounds for estimating non-local background, i.e. successfully identifying a ROI as taught by Curry et al. at paragraph [0020], last 10 lines and paragraph [0021]. Therefore, one of ordinary skill in the art could have applied this known technique in the same way to the image analysis taught by Parsons et al. and the results would have been predictable to one of ordinary skill.

Parsons et al. and Curry et al. suggest, but do not explicitly teach ranking, in a combinatorial manner, the extracted features based on feature performance. Parsons et al. suggests because Parsons et al. at col. 14, lines 40-45 further discusses selecting particular features to quantify different attributes of the temperature response for each pixel, which suggests ranking the extracted features from each pixel. Parsons et al. clearly recognizes more and less valuable feature values, which can easily be ranked

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and filtered accordingly before such feature vector values are put through a classifier for classification.

Sabol et al. also teach a method of image analysis of tissue samples and teach at paragraph [0055] and claim 40 ranking extracted features based on feature performance using an optimizing algorithm, wherein the algorithm runs through an iterative ranking method, which reads on the broad and general reiterative feature of combinatorial algorithms. However, Sabol et al. do not explicitly state using a combinatorial algorithm in the taught ranking method.

Echaz et al. at claims 95 and 97 teach specifically using a combinatorial algorithm for ranking extracted features.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have used a combinatorial algorithm as taught by Echaz et al. for use in a ranking method as taught by Sabol et al. for feature vectors in order to use the most desirable feature values for classification as taught by Parsons et al. and Curry et al. Combinatorial algorithms and Ranking methods are not new methods to the art and one of ordinary skill would immediately envisage the option of implementing such a method step and therefore would not be considered as being an unobvious step that produced unpredictable results. One of ordinary skill in the art would have recognized that applying the known techniques would have yielded predictable results.

Furthermore, the differences between the claimed invention and the prior art were encompassed in known variations or in a principal known in the prior art.

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The combination of Sabol et al., Echauz et al., Curry et al., and Parsons et al. do not teach a method of utilizing image analysis for use in a laser capture microdissection. However, Parsons et al. discusses at col. 15, lines 1-15 and col. 16, analyzing image data to classify tissues as malignant or benign and discusses transmitting this data to an appropriate professional. This invention relates to diagnosing tissues, which are cancerous and would need to be removed.

Levenson et al. at col. 2, lines 45-61 teaches a method of laser capture microdissection after target image analysis.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the analysis and diagnosing methods taught by the combination of references including Parsons et al. with the method of laser capture microdissection taught by Levenson et al. because after diagnosing an individual with cancer it is a necessary step to remove the benign or potentially malignant tumor from the patient. In addition, it would be an inherent step in the process where the information obtained by performing the image analysis steps of Parsons et al. would be transmitted and communicated to the station used to perform the laser capture microdissection.

Parsons et al. at col. 15, lines 39-67 teaches the resulting classified image data may be stored for subsequent analysis as in claims 4-5.

Parsons et al. does not explicitly teach the analogous steps of claim 1 for a second and third method of processing called subimage processing as in claims 6-18 and 30-35.

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However, Parsons et al. at col. 15, lines 39-67 and col. 16, recognizes the potential application of subsequent analysis, which reads on a second and third method of processing or subimage processing. Parsons et al. envisions further analysis steps being performed on the initial image data analysis used to initially classify the tissue at a pixel by pixel level of processing. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to further perform subimage analysis on the classified tissue to further narrow down a classified region of tissue and further ensure accurate results of the classified tissue. Parsons et al. teaches a method of classifying a region of interest within a tissue on a pixel by pixel level of interest and to perform further subimage processing is clearly within the envisioned scope of the instant invention. Because Parsons et al. classifies the tissue on a pixel by pixel level, it is further obvious to envision further levels of processing on the exact pixels, which fall into the category of a classified cancer. Therefore, the performance of subimage processing is not considered an obvious variation which would result in unpredictable results, but rather is an obvious variation as discussed above.

Furthermore, Parsons et al. teach at col. 6, lines 45-50 that more than one image set, which comprises many image frames may be used and selected by a technician for a particular classifier. Parsons et al. at col. 7 teach that the process may be iterative wherein at any given time another image set may be acquired and processed, which reads on claim 36.

Response to Arguments

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Applicant's arguments filed 4/21/2009 are moot with regards to the newly applied rejection.

However, with regards to applicant's arguments: applicant argues that Parsons does not appear to teach or suggest ranking the extracted features from the ROI and non-ROI based on feature performance.

Applicant's arguments are not found persuasive because the Office Action makes the rejection under 35 U.S.C. 103 wherein it was stated as such that Parsons suggest, but do not explicitly teach said limitation. However, the combination of references teach said limitation as stated in the instant Office Action above.

Applicant further argues that one of ordinary skill in the art would not have combined the applied references.

Applicant's arguments are not found persuasive as the field of bioinformatics encompasses many different disciplines where those of ordinary skill in the art routinely look for to other fields of endeavors for solving problems. In the instant case one of ordinary skill in the art would have had good reason to pursue known options in other applications of image processing to resolve current issues or problems. Therefore, one of ordinary skill in the art would have good reason to combine known methods used for analyzing images whether directly or indirectly related.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Borin can be reached via telephone (571)-272-0713.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

/Michael Borin/

Primary Examiner, Art Unit 1631